

Amendments to the Claims: This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

1. (Previously Presented) A method for the sterilization of a labile glucocorticosteroid, comprising the step of applying moist heat to an aqueous suspension of a labile glucocorticosteroid for a sterilizing-effective time, wherein at least 70% of the glucocorticosteroid is in the form of a suspension during heating and at least one surfactant is present in the aqueous suspension during heating.
2. (Previously Presented) A method for the sterilization of a glucocorticosteroid, comprising the step of heating an aqueous suspension of a glucocorticosteroid, wherein the glucocorticosteroid has a sufficiently low solubility in water and is used in a sufficient amount that at least 70% of the glucocorticosteroid is in the form of a suspension during heating and wherein at least one surfactant is present in the aqueous suspension during heating.
3. (Cancelled)
4. (Previously presented) The method of claim 2, wherein said heating is at a temperature of from about 101° C to about 145° C.
5. (Previously presented) The method of claim 2, wherein said heating is carried out by autoclaving.
6. (Previously presented) The method of claim 2, wherein said heating is carried out for about 2 to about 180 minutes.
7. (Cancelled)
8. (Previously Presented) The method of claim 1, wherein the surfactant is present during heating at a concentration of from about 0.75 mg/ml to about 60 mg/ml.
9. (Previously presented) The method of claim 2, wherein the glucocorticosteroid is budesonide or beclomethasone dipropionate.

10. (Previously presented) The method of claim 9, wherein said glucocorticosteroid is budesonide, and the heating is carried out at 121° C for about 20-30 minutes or at 110° C for about 120 minutes.

11. (Previously presented) The method of claim 9, wherein said glucocorticosteroid is beclomethasone dipropionate, and the heating carried out at 121° C for about 20-30 minutes or at 110° C for about 120 minutes.

12. (Cancelled)

13. (Previously presented) A method for the sterilization of budesonide, comprising the step of heating an aqueous suspension of budesonide at a concentration of from about 15 mg/ml to about 150 mg/ml at a temperature of from about 101° C to about 145° C for about 2 to about 180 minutes, wherein at least 70% of the budesonide is in the form of a suspension during heating and at least one surfactant is present in the aqueous suspension during heating.

14. (Previously presented) The method of claim 13, further comprising the step of diluting the aqueous suspension to a pharmaceutically suitable concentration.

15. (Withdrawn from consideration) A composition obtainable by

(i) applying moist heat to a suspension of a labile glucocorticosteroid for a sterilizing-effective time and wherein the glucocorticosteroid is at a concentration of from about 15mg/ml to about 150mg/ml;

(ii) heating an aqueous suspension of a glucocorticosteroid having a sufficiently low solubility in water, and used in a sufficient amount that at least 50% of the glucocorticosteroid is in the form of a suspension during said heating; or

(iii) heating an aqueous suspension of a glucocorticosteroid at a concentration of from about 15mg/ml to about 150mg/ml at a temperature of from about 101°C to about 145°C for about 2 to about 180 minutes.

16. (Withdrawn from consideration) A sterile aqueous suspension comprising a glucocorticosteroid obtained by

(i) applying moist heat to a suspension of a labile glucocorticosteroid for a sterilizing-effective time and wherein the glucocorticosteroid is at a concentration of from about 15mg/ml to about 150mg/ml;

(ii) heating an aqueous suspension of a glucocorticosteroid having a sufficiently low solubility in water, and used in a sufficient amount that at least 50% of the glucocorticosteroid is in the form of a suspension during said heating; or

(iii) heating an aqueous suspension of a glucocorticosteroid at a concentration of from about 15mg/ml to about 150mg/ml at a temperature of from about 101°C to about 145°C for about 2 to about 180 minutes,

wherein the particle size of the glucocorticosteroid is such that the Dv100 is less than 20 μ m, the Dv90 is less than 10 μ m and the Dv50 is less than 5 μ m.

17. (Withdrawn from consideration) A sterile aqueous budesonide suspension obtained by

i) applying moist heat to a suspension of a labile glucocorticosteroid for a sterilizing-effective time and wherein the glucocorticosteroid is at a concentration of from about 15mg/ml to about 150mg/ml;

(ii) heating an aqueous suspension of a glucocorticosteroid having a sufficiently low solubility in water, and used in a sufficient amount that at least 50% of the glucocorticosteroid is in the form of a suspension during said heating; or

(iii) heating an aqueous suspension of a glucocorticosteroid at a concentration of from about 15mg/ml to about 150mg/ml at a temperature of from about 101°C to about 145°C for about 2 to about 180 minutes,

wherein the suspension comprises less than 0.2% by weight of 1,2-dihydro budesonide based on the amount of budesonide.